



DEPARTMENT: NC DHHS Privacy and Security Office	POLICY NAME: HIPAA Hybrid Entity Designation
PAGES 1 of 4	REPLACES POLICY DATED: 3/25/19
EFFECTIVE DATE:	ORIGINAL EFFECTIVE DATE: 3/25/19
REVISED DATE: 4/1/2020	APPROVED DATE: 3/22/19
APPROVED BY: Pyreddy Reddy, CISO; Sam Gibbs, Deputy Secretary IT Operations	

SCOPE:

This policy establishes guidelines for the proper use of the hybrid entity designation for NC DHHS Divisions and Offices as defined by the HIPAA Privacy Rule and Security Rule Standards.

DEFINITIONS:

Covered Entity- a health plan, health care clearinghouse, or a health care provider who electronically transmits any protected health information (PHI) in connection with transactions that include medical, billing payment, or insurance coverage for which HHS has adopted standards.

Hybrid Entity- a single legal entity that is a covered entity, performs business activities that include both covered and noncovered functions, and designates its health care components as provided in the Privacy Rule.

Protected Health Information (PHI)- Any individually identifiable health information, including genetic information and demographic information, collected from an individual that is created or received by a covered entity.

Healthcare Component- NC DHHS Divisions and Offices that operate as a healthcare plan, a healthcare provider, or healthcare clearing house that use, create, or disclose protected health information (PHI).

PURPOSE:

To assess NC DHHS Divisions/Offices operations for appropriate designation as a HIPAA Covered Entity or Hybrid Entity as defined by the Health Insurance Portability and Accountability Act (HIPAA) and in compliance with HIPAA Privacy Standards, Security Standards, 45 CFR Parts 160, 45 CFR Parts 164, and components of the American Recovery and Reinvestment Act (ARRA)

POLICY:

NC DHHS Divisions and Offices shall be assessed for appropriate designation as a Covered Entity or Hybrid Entity. NC DHHS Divisions and Offices performing both covered and non-covered



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functions, shall be designated as a hybrid entity under the HIPAA Privacy and Security Standards. The health care components of the hybrid DHHS agency, including all business associate functions, must comply with all the requirements of the HIPAA Privacy and Security Standards. The non-healthcare components of the hybrid entity are not covered by the HIPAA Privacy Standards.

Initial Coverage Determination

The initial coverage determination will be scheduled with the PSO Coordinator, the NC DHHS Division or Office designated Privacy Officer or Security Officer. The determination shall be documented and retained for (six) 6 years.

Subsequent Coverage Determination Notification

Subsequent coverage determination notification shall be initiated by the NC DHHS Division or Office. On the anniversary month of the prior coverage determination assessment, the NC DHHS Division or Office shall review their internal operations and notify the PSO Coordinator of the following:

1. Annual documentation of new programs or processes that could change the determination from Non-Covered Entity to Hybrid Entity,
2. Annual documentation of new programs or processes that could change the determination from Hybrid Entity to Non-Covered entity,
3. Annual documentation of "No Change in Status" if applicable.

The division office shall submit the form titled "Program/Section Change for Hybrid Entity Determination" to notify the PSO office of any new program or section.

The PSO office shall retain all documentation provided by Divisions and Offices that have complied with notification requirements. NC DHHS Divisions or Offices that have not notified the PSO coordinator will be contacted and given 30 days to respond with status updates. NC DHHS Divisions



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or Offices that report any changes will be contacted to complete the formal coverage determination questionnaire.

Segregation of Functions.

NC DHHS Divisions and Offices must segregate all healthcare components from the non-healthcare components and ensure the following;

1. Where possible, staff and office space should be segregated. Where staff are not segregated, the staff must not use or disclose protected health information (PHI) created or received during their work for the health care component in a manner prohibited by the Privacy Standards;
2. Reasonably ensure information collected by the non-healthcare component is not filed or electronically intermingled with the designated record set;
3. Reasonably ensure information collected by the health care component is not filed or electronically intermingled with information collected during non-healthcare functions. If the information is intermingled, PHI must never be accessed by the non-healthcare component;
4. Ensure information is not shared between the healthcare component and the non-healthcare component without a Memorandum of Agreement/Understanding (MOA/MOU). Please refer to the DHHS MOA/MOU form/template.

ENFORCEMENT

For questions or clarification on any of the information contained in this policy, for general questions about department-wide policies and procedures, contact the [DHHS PSO Policy Writer](#).



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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Program/Section Change for Hybrid Entity Determination

Name of Division or Office

Submission Date:

Prior Hybrid Determination:

Prior Designation Date:

a) Entire Division

Check Box

b) Specific section or program

Check Box

Brief Description of the New Program/Section/Process:

Implementation Date:

No Change In Status:

Check Box